



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL -2 1999

6546 '99 JUL -6 P1:41

The Honorable Edward M. Kennedy
United States Senator
2400 JFK Federal Building.
Boston, Massachusetts 02203

Dear Senator Kennedy:

Thank you for your letter of June 10, 1999 on behalf of Ms. Sheila E. Hill of Derby, Vermont, concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients" FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation (21 CFR 179), are enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR has been extended to July 19, 1999.

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We have forwarded Ms. Hill's correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of irradiated foods will take into account all of the data and information received.

Because Ms. Hill may be concerned about irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this responds to your concerns.

Sincerely,


for Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

Enclosures

cc: Dockets Management Branch
(98N-1038)

The Food and Drug Administration
New England District Office
One Montvale Avenue - 4th Floor
Stoneham, Massachusetts 02180

EDWARD M. KENNEDY
MASSACHUSETTS

Under Code

United States Senate

WASHINGTON, DC 20510-2101

June 10, 1999

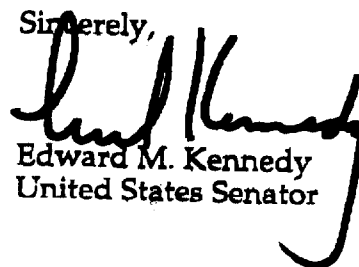
Mr. John Marzilli
Regional Director
Food and Drug Administration
One Montvale Avenue, 4th Floor
Stoneham, MA 02180

Dear Mr. Marzilli:

My assistance has been requested concerning the attached correspondence. I am forwarding this to you for your attention and consideration, and would appreciate your prompt reply directly to me with a copy sent to the constituent.

If you have any questions, please contact Duane Brown in my Boston office at (617) 565-3170. Thank you for your attention to this matter.

Sincerely,


Edward M. Kennedy
United States Senator

2400 JFK Federal Building
Boston, MA 02203

EMK: db

03. 4118

June 1, 1999

Sheila E. Hill
327 Roy Street
Derby, Vt., 05829

FDA

Senator Edward M. Kennedy
2400 John F. Kennedy Federal Building
Boston, Ma. 02203

I have recently been made aware of a frightening development at the Food and Drug Administration, under pressure from food manufacturers and supporters of the nuclear industry. The FDA is considering a rule that would remove labelling requirements for foods treated with radiation.

The public only has until May 18th to voice its objections to this rule. (I've written a letter to the FDA demanding the comment period be extended) Currently, any food treated with radiation during the production process is LABELED with a symbol known as a radura (the international symbol for irradiated foods) and either a statement saying "treated with radiation" or "treated by irradiation." The rule before the FDA would allow manufacturers to sell any and all irradiated foods to the consumer with NO mention of the use of radiation during processing. This is bad for consumers.

Despite the fact that the FDA has determined that radiation is safe for food, many consumers, including myself, my children, my grandchildren, DO NOT WANT TO EAT FOODS TREATED WITH RADIATION! Radiation changes the texture, taste, nutritional value, and composition of foods. Radiation creates a heretofore unseen class of unique radiolytic products that have never been tested for their possible carcinogenic effects on humans. These are things that I do not want to put into my body!

This a clear cut issue of a consumer being able to know what is in their food. We know what the fat, carbohydrate, and vitamin content is in our food, WHY can't we know whether our food has been treated with radiation emanating from some of the most deadly substances known to man? You also have laws in effect with all types of animals, cows, chickens, etc. all you have to do is push those laws for people to "clean up their act" from the farmer to the food manufacturer.

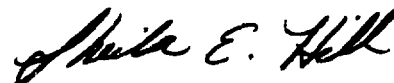
If people are eating this radiation, they will be dead in no time; causing cancer, blood deficiencies, stomach problems, etc. How can America shove "toxic poison" in their food,

(Cont.P.2 of 2)

their children's and grandchildren? If they do this; American citizens have a right to know - PLEASE PUSH TO PUT IT ON FOOD LABELS - SO WE HAVE OUR CHOICE!!!

I, Sheila Hill, and my children and grandchildren, implore you, as a constituent and a friend, to write a letter to the FDA about this issue and ask them why your constituents should be kept in the dark about whether their food has been irradiated and why the comment period has been so short.

Sincerely,



Sheila E. Hill
327 Roy Street
Derby, Vt. 05829
Phone 802-766-4116
Fax 802-766-4966

P.S. Please pass on to all our Representatives and our Congress-
men in Washington, D.C. that we are concerned about food processing. This is bad for consumers.

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(Cont.P.2 of 2)

NEW ENGLAND DISTRICT OFFICE

U. S. FOOD AND DRUG ADMINISTRATION
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STONEHAM, MASSACHUSETTS 02180
TEL: (781)279-1675

NUMBER OF PAGES:
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DATE:

6/17/99

TO:

Mike Ede, OLA

fax 301 443 2567

FROM:

GAIL T. COSTELLO
DIRECTOR, COMPLIANCE BRANCH
FDA - NEW ENGLAND DISTRICT OFFICE

MESSAGE:

Thanks for handling this!

NOTE: If this transmission is illegible or you did not receive all copies, please call me at 781-279-1675 extension 178.

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